DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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August 3, 2001

WARNING LETTER NO. 2001-NOL-43

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Clell M. Rosetti, President
Quality Poultry & Seafood, Inc.
312 Caillavet Street
Biloxi, Mississippi 39530

Dear Mr. Rosetti:

We inspected your firm, located at 312 Caillavet St., Biloxi, Mississippi, on July 2 and 3, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations cause your fresh tuna, cooked shrimp, and crawfish to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HAACP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must implement the monitoring procedure listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of documenting the observation for the presence of ice around fresh tuna and the temperature of the tuna on June 14, 2001, at the receiving critical control point to control histamine formation as listed in your HACCP plan for fresh tuna. In addition, your firm did not follow the monitoring procedure of documenting the time and temperature of each batch of shrimp and crawfish at the cooking critical control point to control pathogen survival as listed in your HACCP plan for cooked shrimp and crawfish.

- You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh tuna does not list monitoring the temperature of the delivery truck used to temporarily store the amberjack, grouper, snapper, and tuna at the receiving critical control point to control histamine formation.

- You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for cooked shrimp, crabs, and crawfish does not list the critical control points of cooling, packaging, and storage for controlling the food safety hazard of pathogen growth and toxin formation. Your firm's HACCP plan for

amberjack, grouper, snapper, and yellow fin tuna does not list the critical control point of storage for controlling the food safety hazard of ciguatera fish poisoning and histamines. In addition, your HACCP plan for picked ready-to-eat crabmeat does not list the critical control point of receiving for controlling the food safety hazards of pathogen growth and toxin formation.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that you made a verbal commitment to correct the deviations. Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of temperature monitoring records, cooking logs, HACCP plans or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

Richard D. Debo
Acting District Director
New Orleans District

Enclosure: Form FDA 483